UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/764,348	01/19/2001	Ivan Santar	P66330US0	7145

7590 08/13/2003

JACOBSON, PRICE, HOLMAN & STERN
PROFESSIONAL LIMITED LIABILITY COMPANY
400 SEVENTH STREET N.W.
WASHINGTON, DC 20004

EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1653	3

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/764,348	SANTAR ET AL.	
	Examiner	Art Unit	
	Anand U Desai	1653	

-- The MAILING DATE of this communication appears on the cover sh t with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 August 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☐ Claim(s) _____ is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-26* is/are rejected.

7)☒ Claim(s) *2,10,12-14 and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☒ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Priority

1. Acknowledgment is made of applicant's claim for foreign priority under 35 U.S.C. 119(a)-(d). The certified copy has been filed in parent Application No. PCT/IE99/00069, filed on July 21, 1999.

2. An application in which the benefits of an earlier application are desired must contain a specific reference to the prior application(s) in the first sentence of the specification or in an application data sheet (37 CFR 1.78(a)(2) and (a)(5)). The specific reference to any prior nonprovisional application must include the relationship (i.e., continuation, divisional, or continuation-in-part) between the applications except when the reference is to a prior application of a CPA assigned the same application number.

Claim Objections

5. Claims 2, 10, 12, 13, 14, 21 are objected to because of the following informalities: There are typographical errors. Appropriate correction is required.

6. Claim 2 is objected to because of the following informalities: There is a typographical error. The word "ar" appears to be intended to read "are".

7. Claim 10 is objected to because of the following informalities: There is a typographical error. The word "polylysin" appears to be intended to read "polylysine". The word "polyarginin" appears to be intended to read "polyarginine".

8. The amendment to the claims filed on 1/19/2001 does not comply with the requirements of 37 CFR 1.121(c) because claim 10 would appear to contain brackets "["

and "]" which are normally intended to indicate deleted matter. Amendments to the claims filed after March 1, 2001 must comply with 37 CFR 1.121(c) which states:

> (c) Claims.
> (1) Amendment by rewriting, directions to cancel or add: Amendments to a claim must be made by rewriting such claim with all changes (e.g., additions, deletions, modifications) included. The rewriting of a claim (with the same number) will be construed as directing the cancellation of the previous version of that claim. A claim may also be canceled by an instruction.
> (i) A rewritten or newly added claim must be in clean form, that is, without markings to indicate the changes that have been made. A parenthetical expression should follow the claim number indicating the status of the claim as amended or newly added (e.g., "amended," "twice amended," or "new").
> (ii) If a claim is amended by rewriting such claim with the same number, the amendment must be accompanied by another version of the rewritten claim, on one or more pages separate from the amendment, marked up to show all the changes relative to the previous version of that claim. A parenthetical expression should follow the claim number indicating the status of the claim, e.g., "amended," "twice amended," etc. The parenthetical expression "amended," "twice amended," etc. should be the same for both the clean version of the claim under paragraph (c)(1)(i) of this section and the marked up version under this paragraph. The changes may be shown by brackets (for deleted matter) or underlining (for added matter), or by any equivalent marking system. A marked up version does not have to be supplied for an added claim or a canceled claim as it is sufficient to state that a particular claim has been added, or canceled.
> (2) A claim canceled by amendment (deleted in its entirety) may be reinstated only by a subsequent amendment presenting the claim as a new claim with a new claim number.

9. Claim 12 is objected to because of the following informalities: There is a typographical error. The word "gelatine" appears to be intended to read "gelatin".

10. Claim 13 is objected to because of the following informalities: There is a typographical error. The word "aminoglucane" appears to be intended to read "aminoglucan".

11. Claim 14 is objected to because of the following informalities: There is a typographical error. The word "compsition" appears to be intended to read "composition". The word "bicompatible" appears to be intended to read "biocompatible".

12. Claim 21 is objected to because of the following informalities: There is a typographical error. The word "gelatine" appears to be intended to read "gelatin".

13. Appropriate correction is required.

14. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

15. Claims 1-3, 5, 14-20, 23, 25, 26 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,372,718. Although the conflicting claims are not identical, they are not patentably distinct from each other because slow release composition is encompassed by compositions claimed in Santar. Slow release formulations of pharmaceutical products are formulations in which pharmaceutical products placed in a composition that releases the pharmaceutical product over time. Thus, the composition of U.S. Patent 6,372,718 encompasses slow release formulations. Santar claims a composition containing polysaccharide material containing polyanhydroglucuronic acid or salts thereof containing, in its polymeric chain, from 8 to 30 per cent by weight of carboxy groups, at least 80 per cent by weight of which are in uronic group form, at most 5 per cent by weight of carbonyl groups, and at most 0.5 per cent by weight of bound nitrogen (claim 1, column 15, lines 25-31; **claims 1, 2, 3, 5, 14, 15**). The polyanhydroglucuronic acid and salts thereof contain in their polymeric chain at most 0.2 percent by weight of bound

nitrogen (claim 2, column 16, lines 1-3; **claim 16**). The molecular mass of the polymeric chain is from $1x10^3$ to $3x10^5$ Daltons (claim 3, column 16, lines 4-6; **claim 17**). The polyanhydroglucuronic acid or salts thereof, wherein the content of carboxyl groups is in the range of from 12 to 26 per cent by weight, at least 95 per cent of which are uronic groups (claim 5, column 16, lines 10-13; **claim 18**). The polyanhydroglucuronic acid or salts thereof, containing at most 1 per cent by weight of carbonyl groups (claim 6, column 16, lines 14-16; **claim 19**). The polyanhydroglucuronic acid or salts thereof, wherein the carbonyl groups are selected from the group consisting of intra- and intermolecular 2,6- and 3,6-hemiacetals, 2,4-hemialdals and C2-C3 aldehydes (claim 7, column 16, lines 17-20; **claim 20**). Santar claims a pharmaceutical composition incorporating stable microdispersed polyanhydroglucuronic acid or salt thereof (claim 10, column 16, lines 28-30; **claim 1, 23, 25, 26**).

16. Claims 1-24 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-33 of U.S. Patent No. 6,596,791. Although the conflicting claims are not identical, they are not patentably distinct from each other because the slow release composition is encompassed by compositions claimed in Santar. Slow release formulations of pharmaceutical products are formulations in which pharmaceutical products placed in a composition that releases the pharmaceutical product over time. Thus, the composition of U.S. Patent 6,372,718 encompasses slow release formulations. Santar et al. claims a biocompatible intermolecular polymer complex of: an anionic component comprising a linear or branched polysaccharide chain wherein at least 5% of the basic strucutural units are those of glucuronic acid; and a non-protein cationic component comprising a linear or branched

natural, semi-synthetic or synthetic oligomer or polymer (**claims 1, 2, 3, 4, 5, 14, 23, 24**). The anionic component comprises polyanhydroglucuronic acid or a salt thereof (**claim 3, 14**). The cationic component contains nitrogen that either carries a positive charge or wherein a positive charge is induced by contact with the polysaccharidic anionic component (**claim 6**). The cationic component is a member selected from the group consisting of an acrylamide, a methacrylamide, and a copolymer of either (**claim 7**). The cationic component is a member selected from the group consisting of a polyacrylamide, a copolymer of hydroxyethylmethacrylate and hyrdroxypropylmethacrylamide, a copolymer of acrylamide, butylacrylate, maleic anhydride, and methylmethacrylate (**claim 8**). The cationic component is a cationised natural polysaccharide, wherein the polysaccharide is a starch, cellulose or gum (**claim 9**). The gum is guargumhydroxypropyltriammonium chloride (**claim 9**). The cationic component is a synthetic or semi-synthetic polyamino acid (**claim 10**). The cationic component is a member selected from the group consisting of polylysin, polyarginin, and α,β-poly-(N-(2-hydroxyethyl)-DL-aspartamide) (**claim 10**). The cationic component is a synthetic anti-fibrinolytic (**claim 11**). The synthetic anti-fibrinolytic is a hexadimethrindibromide (polybren) (**claim 11**). The cationic component is a natural or semi-synthetic peptide (**claim 12**), wherein the peptide is an optionally modified member selected from the group consisting of protamine, gelatine, and fibrinopeptide (**claim 12**). The cationic component is an aminoglucane or a modification thereof (**claim 13**). The cationic component is fractionated chitin or its de-acetylated derivative chitosan (**claim 13**). The aminoglucane is of microbial origin or is isolated from an arthropod shell (**claim 13**). The cationic component is gelatine (**claim 21**). The cationic component is chitosan

(**claim 22**). The anionic component comprises polyanhydroglucuronic acid, which contains in its polymeric chain from 8 to 30 percent by weight of carboxyl groups, at least 80 percent by weight of these groups being uronic groups, at most 5 percent by weight of carbonyl groups, and at most 0.5 percent by weight of bound nitrogen, or a salt thereof (**claims 14, 15**). The polyanhyrdoglucuronic acid or salt thereof contains in its polymeric chain at most 0.2 percent by weight of bound nitrogen (**claim 16**). The polymeric chain of the anionic component has a molecular mass of from $1x10^3$ to $3x10^5$ Daltons (**claim 17**). The molecular mass of the polymeric chain of the anionic component ranges from $5x10^3$ to $1.5x10^5$ Daltons (**claim 17**). The carboxyl groups is in the range of from 12 to 26 percent by weight, at least 95 percent of these groups being uronic groups (**claim 18**). The anionic component contains at most 1 percent by weight of carbonyl groups (**claim 19**). The carbonyl group is a member selected from the group consisting of an intramolecular 2,6-hemiacetal, an intermolecular 2,6 hemiacetal, an intramolecular 3,6 hemiacetal, an intermolecular 3,6 hemiacetal, a 2,4 hemialdal, a C2 aldehyde and a C3 aldehyde (**claim 20**).

Claim Rejections - 35 USC § 112

18. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

19. Claims 1, 2, 7, 8, 9, 11, 12, 13, 14, 15, and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

20. Claim 1 recites the limitation "the polymer chain" in 2nd line at the end of the sentence. There is insufficient antecedent basis for this limitation in the claim.

21. Claim 2 recites the limitation "the basic structural units are glucoronic acid" in line 1 and 2. There is insufficient antecedent basis for this limitation in the claim. The use "of the basic structural units" is not defined in claim 2.

22. Claim 7 is unclear as to what are the derivatives and copolymers because the recitation of acrylamide and methacrylamide are the starting materials and are not, *per se* the derivative nor the copolymer.

22. In claim 8 the "and/or" is unclear as to how the groupings are to be interpreted with regard to is the methylmetacrylate part of all members recited in Markush format in the claim; i.e., is the cationic component polyacrylamide and methylmetacrylate or is it part of only the copolymer of acrylamide and butylacrylate and maleinanhydride and methylmetacrylate?

23. For claim 14 the "and/or" does it mean "and" and "or" at the same time? Suggest applicant use "and" or "or" not both.

24. For claim 15 to which of the multiple different copolymers does "their polymeric chain" refer? To what does the "at most 5 percent by weight of carbonyl groups, and at most 0.5 percent by weight of bound nitrogen" refer?

25. With regard to claims 9, 11, 12, 13 and 17; a broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd.

Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). Regarding claim 9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. See MPEP § 2173.05(d). In the present instance, claim 9, the phrase "such as" renders the claim indefinite because it is unclear whether the limitations following the phrase are part of the claimed invention. In claims 9, 11, 12, 13 change preferably, to wherein said. Claim 9 recites the broad recitation cationised natural polysaccharide, and the claim also recites starch, cellulose, or gum which is the narrower statement of the range/limitation. Change claim 9 from preferably, to wherein said polysaccharide is a starch, cellulose or gum. In the present instance, claim 11 recites the broad recitation synthetic anti-fibrinolytic, and the claim also recites hexadimethrindibromide which is the narrower statement of the range/limitation. In the present instance, claim 12 recites the broad recitation natural or semi-synthetic peptide, and the claim recites protamine, gelatin, fibrinopeptide, or derivatives thereof which is the narrower statement of the range/limitation. In the present instance, claim 13 recites the broad recitation aminoglucan or derivatives thereof, and the claim also recites chitin or de-acetylated derivative chitosan which is the narrower statement of the range/limitation. In the present instance, claim 17 recites the broad recitation 1×10^3 to 3

$x10^5$, and the claim also recites 5×10^3 to 1.5×10^5 which is the narrower statement of the range/limitation.

Claims Rejected

Claims 1-26 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U Desai whose telephone number is (703) 305-4443. The examiner can normally be reached on Monday - Friday 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (703) 308-2923. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0198.

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER

***
August 11, 2003